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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,369	08/24/2001	Darren Y. K. Yap	PD-0464	5015

23608 7590 11/25/2003  
MEDTRONIC MINIMED INC.  
18000 DEVONSHIRE STREET  
NORTHRIDGE, CA 91325-1219

EXAMINER
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RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,369

Applicant(s)

YAP ET AL.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-19, 25-34, 36, 37, 39-57 and 59-67 is/are pending in the application.
- 4a) Of the above claim(s) 6, 25-33, 37, 41-57 and 61-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-18, 34, 36, 39, 40, 59 and 60 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1-5, 7-18, 34, 36, 40, and 60** are rejected under 35 U.S.C. 102(e) as being anticipated by Kakimi et al (US 6,432,089).

Kakimi discloses a plunger 4, and a reservoir (fig. 2). The plunger has a first member 9, and a second member 8. The third component (8) has some vents 85 that would allow a sterilization agent into the first side of the second member. The external side of the first member 9 is adapted to releasably engage a linear actuation member by means of first and second components 6 and 7.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 39 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kakimi et al.

Kakimi discloses the invention substantially as claimed. However, Kakimi fails to disclose the second member being formed from ceramic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Kakimi's second member material to a ceramic one since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Doing so would have provided another kind of stiffer material for the second member.

#### ***Allowable Subject Matter***

5. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments that Kakimi does not disclose a piston including a first member that is adapted to be releasably coupled to a linear actuation member, the examiner disagrees and directs applicant attention to the rejection above. With respect to arguments that Kakimi fails to disclose a second member that includes one or more passages through the second member to permit admittance of a

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sterilization agent to the first side of the second member of the piston, the examiner disagrees. Figures 8-9 shows air vents 85 through the conical portion of component 8. Figure 10 shows a pre-filled syringe with an agent to be injected into the body. It is well known in the art that devices that are going to be used in or used for the body have to be sterilized. The examiner agrees with applicant that Figure 2 shows that the vents are blocked by component 7. However, nowhere in Kakimi's disclosure set forth that the vents are going to be blocked by component 7 during use or that component 7 is permanently fixed upon the vents blocking airflow. Component 7 is free to be rotated within component 8. It is the Examiner's opinion that these vents will allow sterilization gas to go through, and air flow during use (venting).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

November 18, 2003

  
Cris L. Rodriguez  
Examiner  
Art Unit 3763

  
MICHAEL J. HAYES  
PRIMARY EXAMINER